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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/052,212 | 01/16/2002 | Robert Hagen | LIFE-033 | 2190 |
| 24353 | 7590 | 05/27/2004 | | EXAMINER |
| BOZICEVIC, FIELD & FRANCIS LLP 200 MIDDLEFIELD RD SUITE 200 MENLO PARK, CA 94025 | | | ALEXANDER, LYLE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | | 1743 |

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------------|---------------------|-----|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/052,212 | HAGEN ET AL. | |
| | Examiner Lyle A Alexander | Art Unit 1743 | (D) |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 March 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 97-113, 115-125 and 133-144 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 97-113, 115, 118-121, 124, 125 and 133-144 is/are rejected.
 7) Claim(s) 116, 117, 122 and 123 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Upon updating the search new references were found that are pertinent to the subject matter of this application. The following rejection will be non-final. ***Claim***

Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 98-112, 143 and 135 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims do not further limit claim 97 because not "test strips" has been positively claimed. Clarification could be achieved by claiming a test strip in the body of claim 97.

Claim 135 is not clear how the step is accomplished "automatically".

Claim 143 is not clear what type of element is intended for obtaining the sample.

Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 97-98, 101-103, 107, 107-113, 115, 118-121, 124, 133-136 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Eikmeier et al.

Eikmeier et al. teach a system for the storage and dispensing of test strips.

Column 1 lines 35+ teach the system will protect the strips against air humidity and in lines 66 through column 2 teaches the flap presses into the opening of the storage vessel and seal the interior of the storage vessel against moisture. These teachings have been read on the claimed "substantially air and moisture tight seal". Figure 1

teaches a housing(1) comprising a cover(5) and a holder(2) to hold a plurality of test strips(6). Figure 1 further demonstrates a height of at least two thirds of the test strip. The claimed "segregation means" has been read on the spacing of the test strips(6) seen in the figures. With respect to method claim 133, it is noted there is no method step of using an urging element to advance the test strip. As presently written, the claim has been read on the manual removal of a test strip from the pack. The "grasping means" of claim 134 has been read on the fingers of the user removing a test strip.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 125 and 138-144 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eikmeier et al. in view of Berke et al.

See Eikmeier et al. *supra*.

Eikmeier et al. is silent to the claimed threadable engagment of the cover to the base, supplying the instructions for use and the types of test strips dispensed.

Berke et al. teach a test kit that includes detailed instructions for use of the test kit. Supplying instructions is advantageous to insure proper use of kit and proper interpretation of the results. Berke also supplies the required standards and controls to verify the integrity of the results. Improper use of the kit and interpretation of the results could produce false negative/positive results.

It would have been within the skill of the art to modify Eikmeier et al. in view of Berke et al. and supply instructions and controls for the proper use of the kit to gain the above advantages and avoid erroneous results.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. Screw type closures are well known in the art for providing a secure and simple means for sealing a container (e.g. soda bottle caps-a screw type).

It would have been within the skill of the art to further modify Eikmeier et al. and use a screw type closure to achieve the well known and expected functions of a secure and simple closure as optimization of a result effective variable.

The choice of test strip is also a result effective variable based upon the specific analyte of interest. Electrochemical and colorimetric test strips as well colorimeters associated with a test strip dispensing device are well known in the art and have known and expected results and are thus result effective variables.

It would have been within the skill of the art to further modify Eikmeier et al. and incorporate electrochemical , colorimetric or a colorimeter with the test device as optimization of a result effective variable.

Allowable Subject Matter

Claims 99-100 and 104-106 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Claims 116-117 and 122-123 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 97-113, 115-125 and 133-144 have been considered but are moot in view of the new ground(s) of rejection.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pawlowski teaches packaging test strips in a pouch.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander
Primary Examiner
Art Unit 1743

